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**A. INTRODUCTION**

Defendant, Woodbolt Distribution, LLC (“Woodbolt”) submits this Surreply in response to Plaintiff, Natural Alternatives International, Inc.’s (“NAI”) Reply In Support of Plaintiff’s Cross Motion For Summary Judgment of Infringement By Woodbolt and That Patents-In-Suit Are Not Invalid (D.I. 67) (“Reply”).

**B. ARGUMENT**

**1. NAI IMPERMISSIBLY SOUGHT TO CONSTRUE THE PATENT CLAIMS DIFFERENTLY FOR VALIDITY AND INFRINGEMENT ANALYSES**

NAI, in its single combined pleading denominated Opposition, Cross Motion and Motion (D.I. 63), (“Cross Motion”) proposed different claim constructions for its validity and infringement analysis. For its validity analysis NAI proposed a “narrow” claim construction in an attempt to preserve the validity of its claims and avoid novelty-destroying prior art. But because Woodbolt’s accused products and their use are clearly outside the scope of those “narrow” claims, NAI proposed a much different “broad” claim construction in an attempt to cover Woodbolt’s accused products. NAI’s inconsistent claim construction approach is improper, because it violates the well-established rule that claims must be interpreted the same way for both validity and infringement analyses.

Only after Woodbolt, in its Reply (D.I. 66), pointed out NAI’s impermissibly different and inconsistent claim constructions for validity and infringement, did NAI belatedly seek, in its Reply (D.I. 67), to apply the same “narrow” construction for infringement as it did for invalidity. However, NAI has failed to demonstrate that its newly-concocted, narrow claim construction is supported by the intrinsic evidence in the patent file history. Woodbolt will explain below how NAI’s narrow claim construction, by which it seeks to rescue its patents from invalidity, and, its

new arguments and evidence, fail to establish a *prima facie* case of infringement entitling NAI to summary judgment of infringement.

**2. WOODBOLT HAS NOT PROPOSED DIFFERENT CLAIM CONSTRUCTIONS FOR ITS VALIDITY AND INFRINGEMENT ANALYSES**

NAI alleges on page 1 of its Reply that Woodbolt has proposed different claim constructions, one for invalidity, and one for infringement. That is not so. NAI is not correct and its argument presents an inaccurate and misleading picture.

In its Motion for Summary Judgment of Invalidity (D.I. 53), Woodbolt demonstrated that no patentable weight should be given to the term “human dietary supplement” in the composition claims of the ’381 patent, because, as a matter of law, the patentability of a patent claim to a “composition of matter” depends on whether the composition of matter is novel (and unobvious), and no patentable weight is given to how the composition may be “used.” In other words, if a composition is not novel (and unobvious) because it is naturally-occurring, or, has been disclosed in the prior art, a patent cannot be granted for that composition, even if a new “use” has been “discovered” for that composition.<sup>1</sup>

Moreover, the prior art not only discloses many beta-alanine compositions, the prior art also discloses beta-alanine “used” as “human dietary supplements”. Accordingly, Woodbolt simply stated that *even if the “use” term “human dietary supplement” were given patentable weight in the ‘381 patent composition claims (as NAI proposed in its claim construction), those claims were still invalid over the prior art.* Woodbolt acknowledges that the same claim construction must be used in the invalidity and infringement analyses and has said nothing to the

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<sup>1</sup> *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (“The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition”) (citing *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)).

contrary in its moving papers. Thus, unlike NAI, Woodbolt has not taken inconsistent positions in construing the claims for both validity and infringement.

In Woodbolt's Opposition to NAI's Cross Motion that the '381 patent was not invalid, Woodbolt still maintains that, as a matter of law, no patentable weight should be given to the "use" limitation "human dietary supplement" in the '381 patent claims. The claims are invalid, even though NAI contends that the claims are limited to compositions to be "used" as a "human dietary supplement," because the term "human dietary supplement" is merely a "use" limitation not entitled to patentable weight. Simply put, as a matter of law, "use" limitations in patent claims for "compositions of matter" have no patentable weight.

Regardless of the construction proposed by NAI for the '381 patent composition claims, NAI cannot escape the fact that beta-alanine has been disclosed in the prior art as naturally-occurring, that the prior art discloses compositions containing beta-alanine being "used" as *dietary supplements by humans* long before NAI filed for its '381 patent and that the beta-alanine used in the prior art was not a natural or conventional food. Thus, Woodbolt has demonstrated by clear and convincing evidence that the '381 patent is invalid and is entitled to a judgment of invalidity, and, that NAI is certainly not entitled to summary judgment that its '381 patent is not invalid.

**3. NAI HAS NOT DEMONSTRATED THAT THE PREAMBLE TERM  
"HUMAN DIETARY SUPPLEMENT" IS "FUNCTIONAL" AND ENTITLED  
TO PATENTABLE WEIGHT**

On pp. 4-5 of its Reply, NAI argues that there was an unmistakable disavowal of claim scope in the file histories of its patents due to NAI's unilateral statements on how it desired the

claim term “human dietary supplement” to be construed. NAI is mistaken. The two cases NAI cites do not support its position.<sup>2</sup>

NAI’s two cited cases involve admissions made by a patent owner which narrowed the scope of its claims to obtain allowance over close prior art. These admissions prevented the patentee from taking a contrary position in order to then broaden the claims and cover an accused device in a later infringement litigation.

Here the situation is different. Here NAI *unilaterally* made a statement in the file history with the desire that its claims be interpreted in a certain way, but there was no reason why the claims should be interpreted this way. Moreover, NAI has cited no authority which supports its position that *unilateral* statements of a patent applicant could serve to affirmatively later distinguish the claims over later-discovered prior art to somehow save the claims from invalidity. Such unilateral statements cannot be compared to statements made during prosecution to distinguish claims from prior art cited during prosecution. Those statements, as the courts have recognized, may be considered as admissions against interest which estop a patent owner from construing its claims more broadly later to cover accused devices.

NAI cites Manual of Patent Procedure § 2173.05(g) in support of its argument that the term “human dietary supplement” is a “functional” limitation entitled to patentable weight. NAI’s argument here is also misplaced. The preamble term “human dietary supplement” is not a “functional” limitation, but is merely an intended “use” limitation for a composition, which is entirely different. To the extent that the two cases NAI cites<sup>3</sup> gave patentable weight to functional limitations, in those cases the functional terms were “synergistically effective

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<sup>2</sup> These cases are *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 994-95 (Fed.Cir. 2003), and *Pall Corp. v. PTI Techs. Inc.*, 259 F.3d 1383, 1392 (Fed.Cir. 2001).

<sup>3</sup> *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed.Cir.2003) and *Tristrata Tech, Inc. v. ICN Pharms., Inc.*, 313 F.Supp. 2d 405, 410-11 (D.Del. 2004).

amount”, “antibacterially effective amount”, and “enhancing amount”. These terms, all of which include the functional terms “effective” or “enhancing”, served to provide a *minimum amount* of an ingredient needed for a composition to fall within the scope of the claim, and to thereby *exclude* compositions *below* that *minimum amount* which did not provide the recited function of “effectiveness” or “enhancement”.

Here, the term “human dietary supplement” provides no such similar definitional guidance on the “effective” amount of an ingredient to provide an “effective” function. Thus, the term “human dietary supplement” is not a functional limitation, but is merely an “intended use” or “field of use” limitation not entitled to patentable weight.<sup>4</sup>

#### **4. NAI’S REPLY IMPERMISSIBLY RAISES NEW ISSUES AND PRESENTS NEW EVIDENCE, NOT PRESENTED IN ITS CROSS MOTION FOR INFRINGEMENT**

In NAI’s Cross Motion for Infringement (D.I. 63), NAI proposed claim constructions for infringement purposes for the ‘381 Patent and the ’422 patent which did *not* require (1) any specific dose of supplement containing beta-alanine or (2) *multiple* doses of such supplement. Faced with the realization that such a construction of its claims for infringement purposes would render the claims invalid over multiple prior art references, NAI now, for the first time in its Reply (D.I. 67), takes the position that to infringe the claims, the accused product must have (1) a specific *minimum dosage*, and (2) must be administered in *multiple continuous doses* over a “long period of time,” such as “three to four weeks” to cause beta-alanine to accumulate in the user’s muscles.

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<sup>4</sup> This is precisely what Judge Sleet has already considered and decided, despite NAI’s contentions to the contrary, in construing NAI’s similar patents containing the same term in the action styled NAI v. Vital Pharmaceuticals, Inc. (D.Del., C.A. No. 09-626), in an Order Construing the Terms of U.S. Patent Nos. 5,965,596; 6,172,098; and 6,426,361.



It is axiomatic that a party moving for summary judgment should establish a *prima facie* case for being entitled to relief, including demonstrating the absence of any dispute of material fact. Accordingly, NAI should not be permitted, in its Motion for Summary Judgment for Infringement, to change its infringement theory by presenting new proposed claim constructions for the first time in its reply, especially when a reply was not even permitted in this Court's Management Order.

Moreover, NAI has for the first time in its reply submitted new "evidence" on how Woodbolt's customers purportedly use Woodbolt's accused products, and how customers would allegedly follow the instructions on its packaging to infringe NAI's patents. This new evidence, presented by NAI for the first time in its reply, should not be considered, because it is an improper supplementation of the evidence NAI was required to submit in its leading Motion for Infringement.

NAI was required to present a *prima facie* case of infringement in its Cross Motion. It did not do so. The new "evidence" in its Reply is an improper supplementation of its Cross Motion for infringement, and on this basis alone its Cross Motion for Infringement should be denied.

**5. EVEN IF NAI'S NEW CLAIM CONSTRUCTIONS AND EVIDENCE ARE CONSIDERED, NAI HAS FAILED TO DEMONSTRATE INFRINGEMENT**

NAI had the burden of establishing in its Motion for Summary Judgment that no material facts are in dispute. It was completely failed to carry that burden. Even if NAI's new proposed claim constructions and supplemental evidence, submitted for the first time in its reply are considered, NAI still fails to establish infringement because multiple material facts are in dispute.

NAI's proffered evidence for infringement of the '381 patent claims is presented on page 15 of its Reply (D.I. 67) which states:

- [1] [W]oodbolt's labels for C4 provide a dosage – 1 scoop (5.7) grams, which contains 1,500 milligrams of beta-alanine. . . , and
- [2] Under "Suggested Uses" the label tells its customers "DO NOT EXCEED RECOMMENDED DAILY INTAKE" and "Do not use for more than 8 weeks. . ."

NAI then makes a quantum leap from points [1] and [2] by proposing: "The Accused Product *may* be taken at the recommended dosage *every day for eight weeks* as the label on the container states there are *60 servings* in the container" (emphasis added). NAI's logic in proposing its quantum leap proposal from points [1] and [2] is flawed in several respects.

First, NAI has not pointed to any evidence that the label instructs the customer to take the recommended dose *every day*, or, for that matter, at *any* specific repeated frequency. The label simply says "Directed Use on Training Days: take one to two servings (1-2 scoops) 20-30 minutes before training begins ..." Nowhere does the label provide an instruction to take doses at any specific repeated frequency so that beta-alanine will accumulate in the user's muscles.

Second, NAI has not pointed to any evidence that a user would consume the 60 servings in the container within *any* specific period of time, much less the eight weeks that NAI proposes "may" happen. So the total servings in the container do not provide any indication of the frequency of use, even considering the other instructions on the container.

Third, NAI's use of the term "*may*" is a concession that a user "*may not*" use the product in the way NAI alleges. But NAI's burden is to prove that infringement "*is*" occurring, not merely that there is a "possibility" that an infringement "*may*" occur. Thus, NAI has not demonstrated that the accused product C4 (or the other accused products M5 and N-Zero Extreme) infringe claims 1, 11 and 13 of the '381 patent.

For the '422 patent, the deficiency in NAI's showing is just as apparent, if not more so. The '422 patent claims a method of using a human dietary supplement containing beta-alanine. The claims can be directly infringed only by a person who "uses" the supplement. Making or selling a supplement containing beta-alanine are not acts of infringement of the '422 patent because the '422 patent claims require that the supplement be "used" (i.e., consumed) by a user.

NAI has failed to demonstrate that any single user has used an accused product in a way that causes beta-alanine accumulation in the muscles so as to infringe the '422 patent claims under NAI's newly-concocted proposed claim construction. NAI desperately (because there is no other evidence) has pointed to posted videos on YouTube by users in which users stated that they took Woodbolt's products. However, NAI's purported "evidence" on YouTube has several fatal defects.

First, NAI has not established any direct infringement during the term of the '422 patent. The '422 patent did not issue until March 6, 2012. A patent cannot be infringed by anyone before it issues, so any activity by a person before March 6, 2012 cannot be found to infringe. The YouTube "evidence" that NAI points to was posted in February, 2012, before the '422 patent issued, so such "evidence" cannot be used to establish infringement by that user. As NAI acknowledges in its Reply, p. 15, absent "direct infringement" there can be no finding of "indirect infringement", either by inducement or contributory infringement.

Second, NAI has failed to establish that the YouTube video could be introduced at trial in an admissible form, under any rule of evidence. Evidentiary material in support of a motion for summary judgment must be capable of being offered at trial in an admissible form under Rule 56(c)(2), Federal Rules of Civil Procedure. NAI has failed to meet this standard. NAI has not

established that the YouTube individual was under oath, is competent to testify, and would be available for cross-examination. NAI has not even provided the identity of this individual.

Third, even if NAI could somehow establish a “direct infringement” by a user, NAI has not established that Woodbolt “indirectly” infringed, by “inducement” or “contributory” infringement. For “inducement”, NAI has failed to establish that even if a user used the accused products in a way that constitutes a direct infringement under NAI’s newly-concocted claim construction, that Woodbolt has actually “induced” such use by providing instructions or otherwise. Absent such instructions, NAI cannot establish “inducement” by Woodbolt.

NAI has also failed to establish “contributory” infringement. NAI argues on page 17 of its Reply (D.I. 67) that “there is no substantial non-infringing use for these products.” NAI thus recognizes that 35 U.S.C. § 271 (c), which defines “contributory infringement,” provides that contributory infringement can be found only where there is no “substantial non-infringing use.” Under NAI’s newly-concocted claim construction and NAI’s argument, use of a supplement containing beta-alanine in a single or infrequent multiple dose, in the manner disclosed, e.g., by Gardner and Asatoor, must be a “non-infringing use” or else the claims of the ‘381 and ‘422 patents would be invalid over that prior art. Thus, taking a composition containing beta-alanine in the doses disclosed by Asatoor and Gardner,<sup>5</sup> and in the frequency disclosed by Asatoor (two doses two weeks apart) or Gardner (single dose) must be non-infringing under NAI’s claim construction or else the claims would be invalid over this prior art. NAI thus concedes that where the user takes single or infrequent doses, (e.g. as disclosed in Asatoor and Gardner) these

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<sup>5</sup> Woodbolt’s single dosage of one scoop (1500 mg) for an 80 kg subject is 18.75 mg/kg body weight, and two scoops is 37.5 mg/kg body weight, which are substantially the same as the dosages in the prior art of Asatoor (25.6 mg/kg) and Gardner (25 mg/kg). See Woodbolt’s Reply (D.I. 66, p 8, fn 10 & 12).

uses are “substantial non-infringing uses” of a composition containing beta-alanine. NAI thus cannot make its case for contributory infringement.

**C. CONCLUSION**

For the foregoing reasons, even if NAI’s proffered “evidence” in its Reply is considered as a permissible supplementation of NAI’s evidence in its Cross Motion for infringement, NAI has still failed to establish the absence of material fact entitling it to a judgment of infringement as a matter of law. Accordingly, its motion for summary judgment of infringement should be denied.

NAI has also failed to establish that it is entitled to summary judgment of no invalidity. To the contrary, Woodbolt has established by clear and convincing evidence that the ‘381 and ‘422 patents are invalid, and requests summary judgment in its favor on invalidity.

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**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS**

**CERTIFICATE OF SERVICE**

I hereby certify that on September 27, 2012, I caused the foregoing document to be electronically filed with the Clerk of Court using CM/ECF, which will send notification of such filing to all counsel of record.

/s/ Michael Scarpati